1631

Docket No. VIP-0004

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4-3-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kurt Hertogs et al.

Serial No. : 09/580,491 Art Unit: 1631

Filed : May 30, 2003 Examiner: Michael L. Borin

For : NEW MUTATIONAL PROFILES IN HIV-1 PROTEASE AND REVERSE TRANSCRIPTASE CORRELATED WITH PHENOTYPIC DRUG RESISTANCE

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on

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Todd. F. Volyn
(Name of applicant, assignee, or Registered Representative)

Todd F. V
(Signature)

March 24, 2003
(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO OFFICE ACTION

This communication is responsive to the Office Action of December 23, 2002 relating to the application noted above. Applicants request the Examiner reconsider the rejections set forth therein and issue a notice of allowance if view of the following.

The Examiner has rejected the pending claim in this case for lack of enablement. This rejection is respectfully traversed for the following reasons.

The identical rejection was made in an Office Action of December 4, 2001. Applicants responded to that rejection on March 1, 2002. *See*, page 5 of Applicant's response. On March 4, 2002, the Examiner issued a Final Rejection and stated that "Any rejections not reiterated have been withdrawn". The enablement rejection of December 4, 2001 was not reiterated and therefore was withdrawn. As there is no new basis for the rejection and no new art cited, the finding of the previous Examiner should stand. MPEP 706.04. In any event, Applicants stand on their prior response to the rejection of the claim for lack of enablement.

The Examiner has now rejected the pending claim for lack of novelty over the Condra et. al. reference instead of obviousness as was previously asserted. This rejection is respectfully traversed for the following reasons.

The Examiner asserts that Condra shows that mutation 88T correlates with the reduced effectiveness of PIs. His support for this assertion is that Patient O displayed reduced effectiveness in PI treatment and patient O had the 88T mutation. In fact, this is not what the data shows.

Patient O of the Condra reference had the following mutations: I93L, L101, M461, L63P, V77I, N88T, I66V, and T84V. From the data presented it is impossible to determine whether one mutation or a combination of mutations correlates with the reduced effectiveness. All that is known is that the patient's viral isolate showed these mutations.

Elsewhere in the Office Action, the Examiner notes that: "Condra et al teach that the highly variable nature of the

observed amino acid substitutions precludes the identification of simple, invariant rules diagnostic for HIV resistance, no preferred order of appearances of any particular substitution is evident, and that the emergence of phenotypic resistance correlated with the appearance of substitutions at various numbers of amino acid residues among at least 11 sites in HIV protease (rather than just one site as instantly claimed)." The Examiner then goes on to note that Condra stated that no single mutation can be correlated with reduced PI effectiveness. Page 5 of the Office Action. It is inconsistent that on the one hand, a list of mutations means nothing with respect to correlation of a single mutation and PI effectiveness, yet on the other hand it renders that same mutation non-novel. Accordingly, the novelty rejection should be removed. For the reasons set forth in the previously filed Appeal Brief, neither does the Condra reference render the instant application obvious.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 10-0750/VIP-0004/TFV. This sheet is submitted in triplicate.

Respectfully submitted,

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